

## EXHIBIT “F”



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
ROCKVILLE, MARYLAND 20857

FEB 12 1981

Mr. John G. Adams, President  
Flavor and Extract Manufacturers' Association  
of the United States  
900 17th Street, N.W.  
Washington, D.C. 20006

Re: Docket No. 80A-0209

Dear Mr. Adams:

This is in response to your letter of May 16, 1980, in which you requested that advisory opinion status be conferred on the advice contained in the letter of October 30, 1979, from Mr. R. E. Newberry, Bureau of Foods, to Mr. Daniel R. Thompson, regarding labeling of ice cream products flavored with vanilla, vanillin, and other natural flavors.

I agree that the policy in that letter is accurate and complete. I also believe that advisory opinion status for that advice would permit the public to rely on a single interpretation of the regulation, thus reducing the confusion that apparently exists in the industry. Therefore, in order that there be no misunderstanding as to what our policy is in regard to the name of an ice cream product in which the flavor consists of one ounce of vanillin per unit of vanilla constituent and any flavor from a non-vanilla bean source, I am restating as an advisory opinion the advice contained in Mr. Newberry's letter to Mr. Thompson; that is:

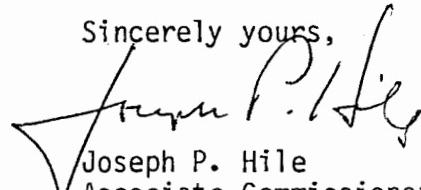
"The ice cream standard under 21 CFR 135.110(e)(5)(i) states that an artificial flavor simulating the characterizing flavor shall be deemed to predominate in the case of vanilla beans or vanilla extract used in combination with vanillin, if the amount of vanillin used is greater than one ounce per unit of vanilla constituent as that term is defined in §169.3(c). Consequently, an ice cream manufacturer could not call his product 'vanilla flavored ice cream' (Category II) if the flavor consisted of one ounce of vanillin per unit of vanilla constituent and any flavor from a non-vanilla bean source (which simulates, resembles, or reinforces the vanilla flavor) is added to the product. The non-vanilla flavor is deemed

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to simulate vanilla if the addition of the non-vanilla flavor results in a reduction in the amount of vanilla bean derived flavor that would otherwise be used in a vanilla flavored ice cream. Ice cream made from such a product would come under category III and have to be labeled as 'artificial vanilla'."

If we can be of further service, please let us know.

Sincerely yours,



Joseph P. Hile  
Associate Commissioner  
for Regulatory Affairs